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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,230	05/08/2001	John Hamilton	111590-121 (US2)	4015

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/851,230	**Applicant(s)** HAMILTON ET AL.	
	Examiner Michail A. Belyavskyi	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *26 May 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112, first, New Matter.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: ~~_____~~.
   Claim(s) objected to: ~~_____~~.
   Claim(s) rejected: *29-34*.
   Claim(s) withdrawn from consideration: ~~_____~~.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached .
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

1. Claims 29-33 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,460 for the same reasons set forth in the previous Office Action, mailed 11/30/04.

Applicant's arguments, filed 5/24/05 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) US Patent '460 describes the identification and use of synthetic peptides which mimic GM-CFS and while US Patent '460 indicates that such GM-CFS peptide mimetics may be used as anti-inflammatory agents, this teaching is insufficient to infer that antibodies specific for GM-CFS are useful for ameliorating inflammation.

Contrary to Applicant's assertion, it is the Examiner position US Patent '460 teaches a method for ameliorating the effects of inflammation including rheumatoid arthritis in a mammal , comprising administering to said mammal a therapeutically effective amount of an M-CSF antigen or antibody to M-CSF antibody wherein M-CSF including human M-CSF (see entire document, Abstract and columns 5 and 9 in particular). US Patent '460 teaches that antibody is monoclonal antibody (see overlapping columns 5 and 6 in particular). In other words, US Patent teaches a method for treating inflammation, including rheumatoid arthritis in a mammal using method of active immunization with M-CSF antigen or anti –antibodies to M-CSF.

Claims 30 and 33 are included because the claimed functional limitation would be inherent properties of the referenced antibodies against GM-CSF, because the claimed method for ameliorating the effects of inflammation and the referenced method using the same antibodies against GM-CSF. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The reference teaching anticipates the claimed invention

2. Claim 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,837,460 in view of US Patent 5444153 or US Patent 5662609 for the same reasons set forth in the previous Office Action, mailed 11/30/04

Applicant's arguments, filed 05/24/05 have been fully considered, but have not been found convincing.

Applicant asserts that since US Patent '460 does not anticipate the invention, they should not be used as the primary references and should be removed.

As has been discussed supra, it is the Examiner position that US Patent '460 do anticipate the invention and thus can be used as the primary references.

The teachings of US Patent 5,837,460 have been discussed, supra.

The claimed invention differs from the reference teaching in that the US Patent 5,837,460 do not teach a method for ameliorating the effects of inflammation in a subject comprising administering antibodies against GM-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

US Patent '153 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA (see entire document, Abstract column 2 and column 5, lines 55-65, and column 6 in particular).

US Patent '609 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA or inhibitors of agents which inhibits the effects of inflammatory mediators (see entire document, column 4 and column 6 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '153 or US Patent '609 to those of WO 00/09561 or US Patent 5,837,460 to obtain a claimed method for ameliorating the effects of inflammation in a subject comprising administering antibodies against GM-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators can be used in the a method of treating inflammatory diseases as taught by US Patent '153 or US Patent '609 and can be combined with a method of treating inflammatory diseases in patients taught by WO 00/09561 or JP 2000198799 or US Patent 5,837,460. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 6, 2005

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